

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

SHERRY L. JONES

Plaintiff,

vs.

BLACKSTONE MEDICAL, INC., SCT,
INC., MEDSOURCE TECHNOLOGIES,
L.L.C., AND FAIRVIEW MACHINE
COMPANY

Defendants.

§
§
§
§
§
§
§
§
§
§

CAUSE NO. 6:07-CV-00455

**REPLY BRIEF IN SUPPORT OF DEFENDANT MEDSOURCE'S
MOTION TO DISMISS**

Defendant MedSource Technologies, Inc. ("MedSource") files its Reply Brief in support of its Motion to Dismiss and argues that Plaintiff fails to meet her burden to dispute or otherwise legally challenge the grounds supporting MedSource's Motion to Dismiss and the Motion to Dismiss, therefore, should be granted.

A. ISSUES NOT DISPUTED BY PLAINTIFF'S RESPONSE

1. MedSource is not the manufacturer of the component part at issue, the "top-locking plate".
2. MedSource is a "Biomaterials Supplier" as defined by the Biomaterials Access Assurance Act ("BAAA"), 21 U.S.C. § 1602.
3. MedSource is not a "seller" or "manufacturer" under the BAAA, 21 U.S.C. §§ 1602, 1604(b), (c).

4. The component part, the top-locking plate, met all of Blackstone's contractual requirements and specifications, as required under § 1604(d) of the BAAA to protect MedSource from liability for any alleged defect in the component.

B. MEDSOURCE DID NOT MANUFACTURE THE COMPONENT PART

MedSource provided sworn testimony that it did not manufacture the top-locking plate and Plaintiff, in response and by her Sixth Amended Complaint, has brought suit against the actual manufacturer of that component part (a point she fails to mention in her Response to the Motion to Dismiss). Plaintiff does not challenge this sworn testimony or argue that the sworn testimony is untrue. As such, MedSource is protected from liability under the BAAA as well as TEX.CIV.PRAC.& REM.CODE § 82.003.

C. MEDSOURCE IS PROTECTED UNDER THE BAAA

Plaintiff argues that the BAAA is not intended to protect medical device component manufacturers and asserts an alleged "suggestion" of intent to exclude component parts to medical devices that does not exist anywhere in the statutory language or in the BAAA's "Findings". Plaintiff's argument is not supported either by the statutory language or any other authority and is actually directly negated and contradicted by the language of the BAAA. Indeed, this Court has already ruled against Plaintiff on this very argument, finding that "Jones' interpretation of the Act runs contrary to the statutory language" and further finding that "the literal language of [21 U.S.C. § 1604(3)] envisions the situation where a manufacturer of a medical device contracts with another manufacturer to produce a specific component part that will be incorporated into a medical device." See the Court's November 10, 2008 Order on Defendant Disanto Technology, Inc.'s Motion to Dismiss, p. 4.

Plaintiff boldly mis-cites §1601(3)(B) and the obvious intent of that particular Finding. Almost every sub-section to § 1601 of the BAAA (Findings), mentions medical devices and the danger that litigation and potential litigation has on the availability of raw materials and component parts for medical devices, clearly intending to protect such suppliers and manufacturers. Plaintiff further suggests that component manufacturers or sellers who know their parts will be incorporated into a medical device are excepted from the protections of the BAAA. However, nowhere in the language of the BAAA is it even suggested that the seller must be ignorant of the use of its part by the buyer as a prerequisite to protection under the BAAA.

Plaintiff does not challenge any of the grounds on which MedSource alleges it is protected under the BAAA (that MedSource is not deemed a “manufacturer” or “seller” under the BAAA and if the BAAA applies, it protects MedSource as a component part supplier). Because MedSource, as a component parts supplier, is protected under the BAAA for any liability for any alleged defect in the medical device at issue in Plaintiff’s lawsuit, dismissal is proper under 21 U.S.C. § 1605(c)(3).

D. MEDSOURCE MET ITS CONTRACTUAL SPECIFICATIONS AND PLAINTIFF IS NOT ENTITLED TO FURTHER DISCOVERY ON THAT ISSUE

The only issue under the BAAA, § 1604(d), is whether the component part failed to meet applicable contractual requirements or specifications, not whether the component part as designed was “defective” by design or manufacture. That is, once the component part supplier delivers its part and that part is accepted as having complied with contractual design and manufacturing specifications, the inquiry under the BAAA is complete and the component supplier has the protections of that statute. Whether the specified and required design and manufacturing processes render the component in any way “defective” is not an inquiry that involves the component manufacturer or seller under the express language of the BAAA.

MedSource provided sworn testimony in support of its Motion to Dismiss that the component part at issue was accepted by and met all of Blackstone's contractual requirements and specifications. *See* the Affidavit of Michelle Auclair, ¶7 ("The component part that MedSource supplied to Blackstone Medical was inspected and accepted by Blackstone Medical per the contractual requirements and specifications that were supplied."). Plaintiff purports to challenge this evidence by a mis-representation of the record before this Court. Plaintiff asserts "Blackstone has claimed that Defendant MedSource, the supplier of the top locking plate in the product at issue, did not comply with contractual specifications/requirements in the manufacture of the top locking plate." There is no such claim before this Court from Blackstone. In fact, in response to Plaintiff's allegation in her Fifth Amended Complaint that "MedSource failed to comply with the specifications for manufacture provided to ... MedSource by Defendant Blackstone", Blackstone specifically **denied** that allegation in its answer to Plaintiff's Complaint (*see* ¶ 26 of Blackstone's Answer to Plaintiff's Fifth Amended Complaint: "Defendant denies the allegations contained in Paragraph 26 to the extent that they relate and pertain to Blackstone Medical, Inc.").

Moreover, Plaintiff admits to the Court that "*All blueprints, purchase orders for parts, and contracts between Blackstone and Defendant MedSource appear to have been produced by the parties throughout the course of litigation to date.*" (Italics in original). Plaintiff, significantly, does not rely on any such documentary evidence or other written discovery to support any assertion that the component part did not meet contractual specifications. As she admits, therefore, Plaintiff has the contractual requirements and specifications and the certifications of compliance - she does not challenge those or put before this court any documentary evidence that MedSource's sworn affidavit testimony is not truthful. Without such evidence which would be readily available from all of the documents produced in this case, Plaintiff simply does not meet her burden to prevent a dismissal

under the BAAA. Even assuming only for the purposes of this Motion to Dismiss that the component part is “defective” (which MedSource denies), that issue does not relate to MedSource. Once MedSource met its contractual requirements and the part met with all contractual specifications, it is protected from suit under the BAAA.

E. MEDSOURCE’S COMPLIANCE WITH CONTRACTUAL SPECIFICATIONS RELIEVES IT OF LIABILITY UNDER TEX. CIV. PRAC. & REM. CODE §82.003

Even assuming again for purposes of this Motion to Dismiss that MedSource “altered or modified” the component part or that it “knew” of some alleged “defect,” proof of either allegation is irrelevant to the issue of whether Plaintiff can continue her suit against MedSource. Whatever the condition of the component part at the time of its delivery to Blackstone, Blackstone certified and accepted the part as meeting all of its contractual requirements and specifications and the BAAA, therefore, as a matter of law, precludes liability as to MedSource. Plaintiff has before this Court the party on which the law places the responsibility to defend the medical device from the defect allegations made by Plaintiff. Further discovery as to whether the medical device at issue is “defective” is appropriate as to Plaintiff and Blackstone, but not as to any component supplier and certainly not to the component supplier which did not manufacture the component part.

F. CONCLUSION

For the reasons stated in its Motion to Dismiss, the supporting Affidavits, and in this Reply, MedSource is entitled to a dismissal of the claims against it.

Respectfully submitted,

/s/Daena G. Ramsey

Daena G. Ramsey

State Bar No. 08093970

Michelle L. Skinner

State Bar No. 24056336

**VAUGHAN, RAMSEY, BARBERA
& WALVOORD, L.L.P.**

530 South Carrier Parkway

Suite 300

Grand Prairie, Texas 75051

(972) 262-0800

(972) 642-0073 - facsimile

ATTORNEYS FOR DEFENDANT
MEDSOURCE TECHNOLOGIES

CERTIFICATE OF SERVICE

I certify that a true and correct copy of this pleading has been served upon the counsel listed below, via certified mail, return receipt requested on March 13, 2009.

Marshall C. Wood
Cyndia M. Hammond
Norton & Wood, L.L.P.
315 Main Street
P.O. Box 1808
Texarkana, Texas 75504-1808
Attorneys for Plaintiff

and by first class mail upon counsel listed below:

Weldon Todd Parker
The Parker Firm, P.C.
3808 Old Jacksonville Road
Tyler, Texas 75701
Attorney for Blackstone Medical, Inc.

Reid W. Martin
Marisa M. Schouten
Martin Walker, P.C.
522 S. Broadway, Suite 200
Tyler, Texas 75702
Attorneys for SCT, Inc.

/s/Daena G. Ramsey
Daena G. Ramsey